



BPL-003 Demonstrates Rapid and Durable Antidepressant Effects in Treatment-Resistant Depression; Phase 2a Data Published in Journal of Psychopharmacology; Phase 3 Program on Track for Q2 2026 Initiation

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NEW YORK, March 17, 2026 (GLOBE NEWSWIRE) -- AtaiBeckley Inc. (NASDAQ: ATAI) ("AtaiBeckley" or "Company"), a clinical-stage biotechnology company on a mission to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments, today announced the peer-reviewed publication of results from its ongoing four-part Phase 2a study ([NCT05660642](#)) evaluating BPL-003 (mebuprofen benzoate nasal spray) in patients with treatment-resistant depression (TRD). Published in [the Journal of Psychopharmacology](#), the newly reported data come from Cohort 1 – a 12 week, open-label trial of a single 10 mg intranasal dose of BPL-003 in 12 patients with moderate-to-severe TRD who were not taking concomitant antidepressants. BPL-003 produced a mean Montgomery-Åsberg Depression Rating Scale (MADRS) total score reduction of 12.6 points by Day 2 (from a baseline mean of 27.5 to 14.8), which was sustained over 12 weeks to a mean MADRS score of 14.5 at Day 85. A response rate (≥50% MADRS reduction) of 54.5% was observed from the day after dosing through Day 85, and 63.6% of patients achieved remission (MADRS ≤10) at one or more timepoints. Mean Snaith-Hamilton Pleasure Scale (SHAPS) scores also improved from 8.4 at baseline to 1.5 at Day 85, indicating an absence of anhedonia. BPL-003 was well tolerated with no serious adverse events and no treatment withdrawals due to adverse events. Most adverse events were transient and mild-to-moderate in severity.

Following a [successful End-of-Phase 2 \(EOP2\) meeting](#) with the U.S. Food and Drug Administration (FDA) announced in March 2026, the Phase 3 program for BPL-003 in TRD remains on track for initiation in Q2 2026.

"The publication of these findings in the Journal of Psychopharmacology is an important scientific milestone. In this first cohort, we saw a rapid 12.6-point mean reduction in MADRS scores by Day 2, which was sustained through 12 weeks on a single dose," said Srinivas Rao, Co-Founder and Chief Executive Officer of AtaiBeckley. *"We are proud to be advancing a novel treatment designed to deliver rapid, durable results and integrate conveniently into clinical care. With Phase 3 on track to initiate in Q2 2026, these peer-reviewed results reinforce our confidence in BPL-003's potential to meaningfully address a critical unmet need for patients living with treatment-resistant depression."*

Clinical Development Update

The Phase 2a trial comprises four cohorts. Results from Parts 1, 2 and 3 have been previously announced. The first patient has been dosed in the Part 4 cohort, evaluating a two-dose induction regimen (8 mg + 8 mg) of BPL-003 in TRD patients receiving defined antidepressants, with initial data expected in Q4 2026.

About BPL-003

BPL-003 is a patent-protected, proprietary intranasal formulation of mebuprofen benzoate, administered via a nasal spray device used in a previously approved drug product. BPL-003 is designed to deliver rapid and durable effects from a single dose, with a short psychedelic duration, and is being investigated as a potential therapy for treatment-resistant depression (TRD) and alcohol use disorder (AUD). BPL-003 has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration and is covered by granted US, UK and European composition-of-matter patents, with multiple further claims pending in various jurisdictions.

About AtaiBeckley Inc.

AtaiBeckley is a clinical-stage biotechnology company on a mission to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments. AtaiBeckley's pipeline of novel therapies includes BPL-003 (mebuprofen benzoate nasal spray) for treatment-resistant depression (TRD), VLS-01 (DMT buccal film) for TRD and EMP-01 ((R)-MDMA HCl) for social anxiety disorder. BPL-003 is in Phase 3 planning, VLS-01 and EMP-01 are in Phase 2 clinical development. The Company is also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT_{2A}R agonists for opioid use disorder and TRD. These programs aim to create breakthroughs in mental health through transformative interventional psychiatry therapies that can integrate seamlessly into healthcare systems.

For the latest updates and to learn more about the AtaiBeckley mission, visit www.ataibeckley.com or follow the Company on [LinkedIn](#) and on [X](#).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking

statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “anticipate,” “initiate,” “could,” “would,” “project,” “plan,” “potentially,” “preliminary,” “likely,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements relating to, among other things: our business strategy and plans; expectations regarding the outcome of regulatory discussions regarding the development of BPL 003; expectations regarding the advancement into Phase 3 studies in adults with TRD and related milestones; expectations regarding the design of the Phase 3 program; and the potential benefits of BPL-003 for patients with TRD.

Forward-looking statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties that could cause actual results to differ materially from those projected, including, without limitation, the important factors described in the section titled “Risk Factors” in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”), as such factors may be updated from time to time in our quarterly reports and other filings with the SEC. AtaiBeckley disclaims any obligation to update or revise any forward-looking statements contained in this press release, other than to the extent required by applicable law.

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